

### **Remarks**

This communication responds to the Office Action mailed January 29, 2008 for the application captioned above.

The following remarks are respectfully submitted

### **Claim Amendments**

Claim 1 is amended to clarify the language and to incorporate the limitations of claim 5. Claim 5 is canceled, without prejudice or disclaimer of the subject matter therein. Support for these limitations can be found throughout the specification, particularly at pages 7, 12 and original claims 1 and 5.

### **Claim Objections**

Applicants thank the Examiner for the statement that claims 12-28 are objected to, but would be allowable if re-written in independent form.

### **Rejections Under 35 USC § 102**

The Examiner rejected claims 1-2, 7-8 and 29 for alleged anticipation by Bergner US 4,562,829 ("Bergner"), our own prior art. The Examiner asserts that Figure 1 of Bergner discloses a radiopharmaceutical container comprising: a) an inlet arm, b) a hollow column, and c) an outlet arm, wherein the improvement comprises configuring the outlet arm so that it does not protrude into the hollow portion of the column and support means to support the inlet arm and the outlet arm. Applicants respectfully disagree. Bergner Figure 1 is a schematic, block diagram and provides no detail about the generator, 28, which is also not described in detail in the Bergner specification. Thus, one skilled in the art would not understand this reference to teach anything other than the known radionuclide generators, which as, explained in the instant specification, WO 06/026603, p. 12, had outlet arms that extended into the hollow column. Indeed, a similar outlet arm design can be seen in Czaplinski et al US 3,920,995 ("Czaplinski") Fig. 4, in which the outlet arm, referred to as the outlet conduit 20 or the lower portion of the outlet conduit 40, extends into the column. Neither Bergner nor Czaplinski teach nor

suggest the claimed outlet arm of claim 1, which provides better flow and more resistance to blockage than those of the prior art. Furthermore, the Examiner has admitted that Bergner fails to teach the notch in the hollow column at the point where the outlet arm intersects the hollow column required in claim 1. See OA, p5 (“Bergner lacks: An improved pharmaceutical container of claim 1 or 2, wherein a notch is provided in the hollow column at the point where the outflow arm intersects the hollow column”). As explained in the instant specification “[t]he recessed outlet arm and notch near the bottom of the column body greatly reduces the chance of back pressure due to a stopper blocking the outlet arm.” See e.g. WO 06/026603, p. 7. Thus, Bergner fails to anticipate claims 1 and 29.

Bergner also fails to teach the use of the radiation resistant materials claimed in claim 2. Indeed, Bergner is silent about the materials used to prepare the generator, making clear that conventional materials were used. As explained in the instant spec (WO 06/026603, 7-8), in the prior art, to the extent radiation resistant materials were used, they were sufficient to withstand the amount of radiation used for sterilization (typically about 25 kGy), while for the purposes of the present invention a material is radiation resistant or tolerant when it can be exposed to about 145 kGy radiation without adversely affecting function.

Regarding claims 7 and 8, Applicants respectfully point out that Bergner Figure 1 provides absolutely no information about how the column is sealed. The most one can tell from looking at Figure 1 is that the generator 28 has some sort of closure at the top and bottom of the column. However, no information about the type of closure can be gleaned from Figure 1.

In sum, Bergner fails to anticipate claims 1, 2, 7, 8 and 29. Applicants respectfully request that the Examiner withdraw the rejections of claims 1-2, 7, 8 and 29.

**Rejections Under 35 USC § 103**

Claims 3-4 and 9-10 were rejected for alleged obviousness over Bergner. The Examiner admits that Bergner does not disclose the claimed materials (polypropylene, PP 13R9A polypropylene, isoprene/chlorobutyl, bromobutyl and FM 140/0), but asserts that it would have been obvious to select such materials. Applicants respectfully disagree, and, based on the following argument, respectfully request that the Examiner withdraw the rejection of claims 3-4 and 9-10.

As an initial matter, as explained above, Bergner fails to disclose the recessed column arm and notch required by these claims. Furthermore, Bergner is silent about the materials used to prepare the generator, making clear that conventional materials were used. As explained in the instant spec (WO 06/026603, 7-8) in the prior art, to the extent radiation resistant materials were used, they were sufficient to withstand the amount of radiation used for sterilization (typically about 25 kGy), while for the purposes of the present invention a material is radiation resistant or tolerant when it can be exposed to about 145 kGy radiation without adversely affecting function.

Claims 5-6 and 11 were rejected for alleged obviousness over Bergner in view of Czaplinski. The Examiner admits that Bergner lacks the notch in the hollow column at the point where the outflow arm intersects the hollow column of claim 5. However, the Examiner asserts that Czaplinski discloses such a notch at figure 4, 40. Applicants respectfully disagree. In Czaplinski, Item 40 of figure 4, the lower terminus of the outlet conduit (e.g. the outflow arm), extends into the column and the column does not include a notch. This reference fails to disclose the recessed arm or the notch in the hollow column of the instant claims (see Applicants Figs 4 and 1D). In fact Czaplinski teaches away from the notch of the current claims.

Regarding claim 6, the Examiner admits that Bergner does not disclose the claimed basket receptacle area, but asserts that Czaplinski does at column 2, lines 45-59. Applicants respectfully disagree. The passage cited by the Examiner discusses a unitary

molded plastic receptacle holder for the eluent container and the eluate container. This is not part of the generator itself, but rather holds the eluent and eluate containers which in turn are connected to the casing 42 of the generator for use. See, e.g. col. 5, lines 6-20 and line 47 –col. 6, line 4. Clearly Czaplinski neither teaches nor suggests the instant invention, which requires a basket receptacle area inside the generator column comprising one or more notches configured to cooperate with protrusions on the basket to be inserted to insure that the basket is properly seated in the receptacle area (see Fig 1E).

Regarding claim 11, the Examiner admits that Bergner fails to disclose the claimed stoppers, but asserts that Czaplinski discloses the claimed stoppers at figure 4, 17, 16. Items 16 and 17 of Czaplinski Figure 4 are stoppers described at col. 3, lines 46-62, which does not teach or suggest the claimed stoppers in which the top portion has a greater diameter than the bottom portion.

In light of the arguments presented above, Applicants respectfully request that the Examiner withdraw the rejection of claims 5-6 and 11.

Claims 30-31 were rejected for alleged obviousness over Bergner in light of Nijssen et al., US 6,373,068 (“Nijssen”). Regarding claim 30, the Examiner admits that Bergner lacks the first connector tube which attaches to the inlet arm via a Luer lock, and a second connector tube which attaches to the outlet arm via a Luer lock, wherein a portion of each Luer lock is affixed to each of the connector tubes and another portion of the Luer locks is affixed to each of the inlet and outlet arm. However, the Examiner asserts that Nijssen teaches such connector tubes and Luer locks at Column 1, line 65 – column 2, line 3. Applicants respectfully disagree. As an initial matter, neither Bergner nor Nijssen discloses the recessed column arm and notch required by these claims. Furthermore, Nijssen simply states that the irradiation vessel comprises a coupling connection such as a Luer lock. There is no teaching or suggestion that a first connector tube is attached to the inlet arm of a radionuclide generator by a Luer lock and a second connector tube is attached to the outlet arm of a radionuclide generator by a Luer lock

wherein a portion of each Luer lock is affixed to the connector tube and a portion is affixed to the inlet or outlet arm.

Regarding claim 31, the Examiner admits that Bergner does not teach the Luer lock, but asserts that Nijsen discloses such locks. However, the Examiner does not even assert that the combination of Bergner and Nijsen teaches or suggests the claimed radiation resistant materials.

In light of the arguments presented above, Applicants respectfully request that the Examiner withdraw the rejection of claims 30 and 31.

Claims 32-33 and 38-39 were rejected for alleged obviousness over Bergner in view of Nijsen. The Examiner admits that these references fail to disclose the claimed materials or the use of an absorbent material, but asserts that such choices would have been obvious. Applicants respectfully disagree, and, based upon the following arguments, respectfully requests that the Examiner withdraw the rejection of claims 32-33 and 38-39.

As an initial matter, Bergner and Nijsen fail to disclose or suggest the recessed column arm and notch required by these claims. Furthermore, as explained in the instant spec (WO 06/026603, 7-8) in the prior art, to the extent radiation resistant materials were used, they were sufficient to withstand the amount of radiation used for sterilization (typically about 25 kGy), while for the purposes of the present invention, a material is radiation resistant or tolerant when it can be exposed to about 145 kGy radiation without adversely affecting function.

Regarding claims 38-39 inclusion of an absorbent material is not taught or suggested by either reference.

In view of the foregoing, it is submitted that this application is in condition for allowance. Favorable consideration and prompt allowance of the application are respectfully requested. Applicant believes no fee is due to enter the present Amendment. The Commissioner is hereby authorized to charge any additional filing fees required to Deposit Account No. 061910. The Examiner is invited to telephone the undersigned if the Examiner believes it would be useful to advance prosecution.

Respectfully submitted,

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